

REMARKS

The application is amended in a manner to place it in condition for allowance.

Status of the Claims

Claims 32, 37, 39, 42, 44, 46, 51, 53, 56 and 59 are amended to clarify that claimed polyurethane is a solid polyurethane polymer, which is, or is capable of being, dissolved in a solution. Support for the amended claims may be found, for example, at page 8, lines 1-6, page 11, "6. Compositions and kits", items 12) and 13) under "Utility" on pages 12 and 13, and the Examples of the specification.

Claims 32, 36-46, 50-57, and 59-65 remain pending.

Claim Rejections-35 USC §102

Claims 32, 36-37, 39, 43-46, 50-53, 56-57, 59 and 61-65 were rejected under 35 USC §102(e) as being anticipated by PORTER US 20002/0165583 (PORTER). This rejection is respectfully traversed for the reasons the three reasons that follow:

I. Porter does not disclose PU polymer solutions.

PORTER discloses delivering a composition to a vascular site, and (i) precipitating or (ii) polymerizing the composition *in situ*.

Paragraph [0087] PORTER describes the *in situ* precipitation method, which includes dissolving a polymer in a solvent: "...the present invention comprises polymer dissolved in solvent. Several of these compositions are known in the art, as discussed above."

These compositions are discussed in paragraphs [0005] and [0006] of PORTER. Nowhere else are the known polymer solutions discussed before paragraph [0087]. Most significantly, PU is not even mentioned in the long list of the possible polymers of [0005]. So, contrary to the statement made in the Official Action, PORTER does not disclose that the use of PU for embolization is known in [0087]-[0088].

PU is mentioned only in connection with the "main" invention of PORTER, i.e., *in situ* polymerization. *In situ* polymerization involves delivering a prepolymer composition to the site and at least partly polymerizing the composition *in situ* by an activator. See, e.g., the abstract and paragraphs [0016]-[0018]. PORTER specifically notes that a "foamable TDL-based polyurethane prepolymer can be used to foam and cross-link *in situ* upon mixing with water." (Emphasis added.) See, e.g., paragraph [0059].

In view of the above, PORTER solely discloses preparing PU by *in situ* polymerization, and the *in situ* precipitation of the polymer solutions is apparently limited to the polymers listed in [005].

Thus, PORTER fails to disclose (i) dissolving a solid polyurethane polymer, as required by independent claim 32 and dependent claims 36-37, 39, 43-45, (ii) a polyurethane solution formed from a solid polyurethane polymer dissolved in a solvent as recited in independent claim 46 or dependent claims 50-53, 56-57, or (iii) a kit with a solid polyurethane polymer and a solvent that dissolves the polymer, as recited in claim 59, and dependent claims 61-65.

III. A PU prepolymer is neither a solid nor a polymer.

The following three sources describe the properties of PU prepolymers:

- (a) EVANS et al. US 5,702,361 ("EVANS (I)"),
- (b) <http://en.wikipedia.org/wiki/Polyurethane>, and
- (c) <http://www.specialchem4adhesives.com/resources/articles/article.aspx?id=2342>.

Printed copies of (b) and (c) are provided in the appendix.

For example, source (a), i.e., EVANS (I), clearly states that polyurethane prepolymers are liquid. See, e.g., column 7, lines 57-58.

Indeed, source (c) further describes, structurally, how these liquid prepolymers differ from the polymer. As noted in the Introduction, polyurethanes should be prepared because the basic diisocyanate reagents are very reactive and toxic. The prepolymers are obtained by reacting the basic diisocyanate

compounds with a smaller amount of free hydroxyl containing compounds (mainly with diols, under the stoichiometric amount to ensure the presence of free isocyanate groups in the prepolymer formed). These prepolymer compounds are less reactive and toxic, so they are safer. Thus, the prepolymers are starting materials in the preparation of the final PU product (they should be further reacted e.g. with polyol).

Moreover, the prepolymers are reactive mainly diisocyanate type compounds (they can have more than two reactive isocyanate groups, depending on the type of the applied hydroxyl containing reagent), but the PU polymer is an inert substance (See, e.g., the Health and Safety part in source (b)) with higher molecular weight. Such higher molecular weights of the PU are recited, for example, in dependent claims 42 and 56 of the claimed invention.

In light of these three sources, the claimed PU differs from the PU disclosed by PORTER, in that the claimed PU is an inert, solid polymer whereas PORTER is limited to reactive, liquid prepolymers.

Thus, PORTER fails to disclose dissolving a solid polyurethane polymer, as required by independent claim 32 and dependent claims 36-37, 39, 43-45, a polyurethane solution formed from a solid polyurethane polymer dissolved in a solvent as recited in independent claim 46 or dependent claims 50-53, 56-57, or a kit with a solid polyurethane polymer and a solvent that

dissolves the polymer, as recited in claim 59, and dependent claims 61-65.

III. Once polymerized *in situ*, PU is not "dissolved".

After a solid polymer is formed from the PU prepolymer *in situ*, the solid polymer and surrounding solution are not the same as a dissolved polymer that is able to solidify. This is due to the fact that PORTER utilizes cross-linking, which renders these polymers insoluble. See, e.g., paragraphs [0059] and [0066].

Thus, PORTER does not disclose any of the polymers recited in 32, 36-37, 39, 43-46, 50-53, 56-57, 59 and 61-65, which are dissolved or are capable of dissolving in a solvent.

Therefore, for at least the three reasons discussed above PORTER fails to anticipate the claimed invention, and withdrawal of the rejection is respectfully requested.

Claims 32, 36, 43-46, 50, 56-57, 59-62 and 65 were rejected under 35 USC §102(b) as being anticipated by EVANS (I). This rejection is respectfully traversed for the reasons that follow.

EVANS (I) discloses compositions of a polymer or prepolymer and solvent, where the polymer precipitates upon separation with the solvent. See, e.g., the Abstract and column 7, lines 41. EVANS (I) further discloses that "[w]hen the

prepolymer is liquid (as in the case of polyurethanes)", the solvent is not necessary. See, e.g., column 7, lines 57-58. In the case of a liquid prepolymer, a polymer is formed once the prepolymer contacts the blood. See, e.g., column 9, lines 50-60.

Thus, EVANS (I) fails to disclose dissolving a solid polyurethane polymer, a polyurethane solution formed from a solid polyurethane polymer dissolved in a solvent, and a kit with a solid polyurethane polymer and a solvent that dissolves the polymer.

Therefore, claims 32, 36, 43-46, 50, 56-57, 59-62 and 65 are not anticipated by EVANS (I), and withdrawal of the rejection is respectfully requested.

Claims 32, 36, 43-46, 50, 56-57, 59-62 and 65 were rejected under 35 USC §102(e) as being anticipated by EVANS et al. US 6,345,202 ("EVANS (II)"). This rejection is respectfully traversed for the reasons that follow.

The Official Action believes that EVANS II discloses PU, and points to both the Abstract and column 3, line 41 to column 4, line 10.

However, PU is not mentioned in column 3, from line 41. Urethane/carbonate copolymers are discussed here, but these copolymers are not the same as PU, as evidenced by the fact that Table I of EVANS (II) separately discusses the poly(carbonate-urethane) from PU, i.e., a different type of polymer with

different physical properties. Moreover, the claims explicitly recite that claimed PU is obtained by polyaddition reactions of diols and diisocyanates, which excludes poly (carbonate-urethane) copolymers.

While EVANS does mention PU in the Abstract, there is no suggestion that PU is dissolved in a solvent. Indeed, in Table 1, EVANS (II) shows that PU does not dissolve in a solvent, such as DMSO, which is contrary to the claimed invention.

It also should be emphasized that EVANS (II) follows EVANS (I) by approximately 1.5 years, but EVANS (II) still fails to disclose a polymer solution from PU.

Therefore, claims 32, 36, 43-46, 50, 56-57, 59-62 and 65 are not anticipated by EVANS (II), and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §103

Claims 32, 36-46, 50-57, 59-65 were rejected under 35 USC §103(a) as being unpatentable over PORTER US 20002/0165583 (PORTER). This rejection is respectfully traversed for the reasons that follow.

For the reasons discussed above with respect to the anticipation rejection, PORTER fails to disclose the claimed invention. There is nothing in PORTER to suggest utilizing a solid PU polymer which is dissolved in solvent.

Indeed, PORTER teaches away from providing a PU solution, where PU solidifies in the absence of the solvent, as the polymer solutions include a cross-linked polymer. A cross-linked polymer would not be capable of being dissolved in a solvent and re-solidifying in the absence of the solvent.

Therefore, PORTER fails to render obvious Claims 32, 36-46, 50-57, 59-65, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/

Robert A. Madsen, Reg. No. 58,543
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RAM/fb

APPENDIX

Print outs from

- <http://en.wikipedia.org/wiki/Polyurethane>
- <http://www.specialchem4adhesives.com/resources/articles/article.aspx?id=2342>.